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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,073	04/20/2001	Todd C. Sacktor	13492	2721

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,073

Applicant(s)

SACKTOR, TODD C.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-14-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the rejection of the last Office action is withdrawn in view of the new grounds of rejection set forth below.

Response to Amendment

2. The amendment filed 5 November 2004 has been entered. Claims 11, 13, and 15 are examined below. Claims 1-10, 12 and 14 have been cancelled.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Lang et al. (US 2005/0064501).

Lang et al. teach the method of administering chelerythrine as kinase inhibitors for therapy of many diseases including Alzheimer's disease, diabetes mellitus,

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arteriosclerosis, cirrhosis of the liver, Crohn's disease, fibrosing pancreatitis, pulmonary fibrosis and chronic bronchitis (page 1, paragraph 0012-0014, 0030, 0032-0057) Lang et al. teach that the chlerythrine suppresses the activation of the Na⁺ channel (page 1, paragraph 0023, 0052-0057). Lang et al. teach treatment of epileptic seizure with kinase inhibitors (page 2, paragraph 0028). Lang et al. teach diagnosing of epilepsy, hypertension, fibrosing pancreatitis, radiation fibrosis, scleroderma, cystic fibrosis, chronic bronchitis using tissues of brain, Alzheimer's disease, cirrhosis of the liver, Crohn's disease, fibrosing pancreatitis and pulmonary fibrosis, arteriosclerosis, diabetic nephropathy.

The patients with the above listed diseases would have the pain syndrome as well associated with the diseases. The administration of Chlerythrine inherently has the amnesiac effect.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US 2005/0064501) in view of Thiam et al. (FEBS Letter, 1999).

Lang et al. teach the method of administering chelerythrine as kinase inhibitors for therapy of many diseases including Alzheimer's disease, diabetes mellitus, arteriosclerosis, cirrhosis of the liver, Crohn's disease, fibrosing pancreatitis, pulmonary fibrosis and chronic bronchitis (page 1, paragraph 0012-0014, 0030, 0032-0057). Lang et al. teach that the chelerythrine suppresses the activation of the Na⁺ channel (page 1, paragraph 0023, 0052-0057). Lang et al. teach treatment of epileptic seizure with kinase inhibitors (page 2, paragraph 0028). Lang et al. teach diagnosing of epilepsy, hypertension, fibrosing pancreatitis, radiation fibrosis, scleroderma, cystic fibrosis, chronic bronchitis using tissues of brain, Alzheimer's disease, cirrhosis of the liver, Crohn's disease, fibrosing pancreatitis and pulmonary fibrosis, arteriosclerosis, diabetic nephropathy. The patients with the above listed diseases would have the pain syndrome as well associated with the diseases. The administration of Chelerythrine inherently has the amnesiac effect. Lang et al. does not teach the myristoylation pseudosubstrate peptide.

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Thiam et al teach the method of administering palmitoylated modified PCK- ζ pseudosubstrate lipopeptides on HL60 human cells (page 286 and figures 1-3). The claims method step requires administration of a therapeutically effective amount which is met by concentration of 10 μ M (page 287-288). The palmitoylated peptide is a subgenus of myristoylation peptide meeting the claim limitation of claim 13.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Lang et al. by substituting the myristoylated pseudosubstrate peptide of Thiam et al. One of ordinary skill in the art would have been motivated to modify the method of Lang et al. because Lang et al. explicitly consider chelerythrine, Staurosporine or other kinase inhibitors and pseudosubstrate peptide of Thiam et al. is a kinase inhibitor. Furthermore, one of ordinary skill in the art would have been motivated because Thiam et al. is an analogous art with Lang et al. because both use kinase inhibitors.

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. PAK

Michael Pak

Primary Patent Examiner

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12 September 2005